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April 4, 2024
VIA ECF

Honorable Brian R. Martinotti, U.S.D.J.
United States District Court
District of New Jersey
Frank Lautenberg Post Office & U.S. Courthouse
2 Federal Plaza, 3rd Floor
Newark, New Jersey 07102

Honorable Rukhsanah L. Singh, U.S.M.J.
United States District Court
District of New Jersey
Clarkson S. Fisher Fed. Bldg. & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *In re Insulin Pricing Litigation*
Case No. 2:23-md-3080 (BRM/RLS)

Dear Judges Martinotti and Singh:

We write on behalf of Manufacturer Defendants pursuant to the Court's pre-motion filing requirements to seek permission to resolve an issue regarding the MDL's scope that will delay all tracks if not resolved promptly. Unlike the insulin pricing cases that have been litigated before this Court for years, and at odds with the JPML's creation of this "Insulin Pricing" MDL, Mississippi (as well as others in the State Attorney General Track) seeks unfettered discovery into *non*-insulin products called glucagon-like peptide receptor agonists ("GLP-1s"). Those drugs are not insulins. Nor do they share characteristics with insulins that underpin the so-called "Insulin Pricing Scheme" alleged in all of the MDL complaints. Nonetheless, counsel for the State Attorney General ("AG") Track insists that because they tacked a few references to those drugs onto their complaints, the Manufacturer Defendants must start discovery all over again to focus on GLP-1s.

Manufacturer Defendants therefore request leave to file a motion for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c) in *The State of Mississippi, ex rel. Lynn Fitch, Attorney General v. Eli Lilly and Company, et al.*, Case No. 2:23-cv-04364. As discussed below, the Mississippi complaint fails to plead any unlawful conduct regarding GLP-1s and Mississippi's claims about GLP-1s—all of which arise under state law—would also be preempted. The Court should accordingly grant Manufacturer Defendants leave to file a Rule 12(c) motion with respect to Mississippi's GLP-1 claims. Addressing this issue now—instead of waiting until it inevitably arises as a discovery dispute—will reduce the burden on the Court and the parties. The parties conducted a meet and confer regarding this topic on April 2, 2024.

I. The "Insulin Pricing Scheme" and the MDL Are About *Insulin*, Not GLP-1s

Three years ago, the Mississippi Attorney General filed this suit on behalf of the State and Mississippi residents with diabetes under the *parens patriae* doctrine. The complaint alleges that Manufacturer Defendants conspired with pharmacy benefit managers ("PBMs") to inflate the list price of insulin, in what Mississippi describes as an "Insulin Pricing Scheme." 3d Am. Compl. ("TAC") ¶¶ 278–80, *Mississippi v. Eli Lilly &*

Co., No. 21-cv-00674 (S.D. Miss. Feb. 17, 2022), Dkt. 71. The State asserts state-law claims against Manufacturer Defendants for violation of the Mississippi Consumer Protection Act ("MCPA"), unjust enrichment, and civil conspiracy. *Id.* ¶¶ 521, 529, 537.

According to the State, the purported "Insulin Pricing Scheme" has several hallmarks: (1) insulin is a century-old off-patent product that has not "significantly improved over the last twenty (20) years"; (2) Manufacturer Defendants' expenditures on "production" and "research and development" for insulin have not "increased," but rather "decreased," in recent years; and (3) despite this, the price of insulin has "dramatically increased" in "lockstep" since 2003. *Id.* ¶¶ 248, 250, 259, 261, 264–67, 278–86, 289–94.

In four paragraphs, the complaint tries to sweep into the so-called "Insulin Pricing Scheme" a handful of novel, diabetic medications—the GLP-1s.[1] Other plaintiffs in the MDL have since copied the Mississippi complaint's threadbare allegations about GLP-1s. *E.g.,* Compl. ¶¶ 237–38, *Oneida County, N.Y. v. Eli Lilly and Co.*, No. 2:24-cv-00694 (D.N.J. Feb. 6, 2024), Dkt. No. 1.

But the "Insulin Pricing" MDL is about *insulin*, not other medications that some plaintiffs would like to use to expand the scope of these cases. By the State AG Plaintiffs' own admission, these cases "involve the Insulin Pricing Scheme" to "inflate the price of insulin." Brief in Support of Mot. to Transfer, *In re Insulin Pricing Litig.*, MDL No. 3080 (J.P.M.L. May 9, 2023), Dkt. 1-1. Unsurprisingly, each of the "material factual issues" the States' counsel cited to justify this MDL related to the "the price of insulin." *Id.* at 6–7. All of the cases consolidated into the MDL and pending before this Court assert claims that are expressly premised on that supposed scheme related to insulin pricing. The JPML granted the State Attorney General Track's request for an MDL, and it chose this Court given its extensive history overseeing other cases concerning the alleged "insulin pricing scheme." Dkt. 91, Transfer Order at 4, *In re Insulin Pricing Litig.*, MDL No. 3080 (J.P.M.L. Aug. 3, 2023). Indeed, in the prior litigation overseen by this Court, the Manufacturer Defendants produced nearly a million documents related to insulin. As this Court has recognized, a "significant amount of discovery" has been done. 9/12/23 Case Management Conference, Tr. 15:14–25. Leveraging this experience is central to the MDL's efficiencies. To that end, the Court urged the plaintiff groups to coordinate amongst themselves regarding "the exchange . . . of previously produced discovery" so as to avoid "reinventing the wheel." *Id.* 24:4–14.

Despite all of this, counsel for the State Attorney General Track has warned in ongoing discovery meet and confers that they will insist on "full" discovery on GLP-1 products—a massive, unjustified expansion of this MDL that would force the parties to essentially begin discovery anew. The States' approach would inevitably result in discovery disputes, further delaying progress across all tracks of the MDL. In such a dispute, counsel for plaintiffs have indicated that they will take the position that mere

[1] The novel Type 2 diabetes medications that Plaintiffs allege should be included are Trulicity®, Victoza®, Ozempic®, and Soliqua®. Trulicity®, Victoza®, and Ozempic® are GLP-1s. Soliqua® combines a GLP-1 and insulin glargine.

references to GLP-1 drugs in their complaints justify expansive discovery into those drugs—and that such burdensome, irrelevant discovery should ensue despite the absence of any basis, whether factual or legal, to support the contention that these medications are part of the purported Insulin Pricing Scheme.

II. The Court Should Resolve this Threshold Question through a Motion for Partial Judgment on the Pleadings

Manufacturer Defendants respectfully submit that the Court should promptly resolve this issue, and that a motion for partial judgment on the pleadings in Mississippi is an appropriate way to do so. The sole basis that counsel for the AG Track has offered for this expansion of the MDL is the inclusion of a few stray paragraphs in Mississippi's complaint (and others like it). But those allegations do not adequately plead a claim involving those medications, and any claim would be preempted by federal patent law.

First, the Mississippi complaint fails to plead any unlawful conduct regarding GLP-1s, nor does it explain why they are part of the Insulin Pricing Scheme. None of the State's factual allegations about insulin pertain to GLP-1s, which are *not* century-old medications. To the contrary: they are novel drugs that Manufacturer Defendants developed in recent years after spending billions of dollars on research and development. TAC ¶¶ 270, 277. And the complaint fails to plead any unlawful conduct as to GLP-1s. In its 118-page complaint, beyond a smattering of paragraphs that merely note what the products are and a figure showing their prices, the State is entirely silent about GLP-1s. That is insufficient to state a claim under any theory Mississippi is pursuing.

Second, any claim about GLP-1s would be preempted. The GLP-1s identified in the complaint are patent-protected. For such products, Congress—not the states—is "the promulgator of patent policy." *Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1372 (Fed. Cir. 2007). Federal patent law reflects Congress's consideration of the delicate balance between "enabl[ing] innovators to obtain greater profits than could have been obtained if direct competition existed" and "keep[ing] prices reasonable for consumers." *Id.* State laws that seek to regulate the price of "patented prescription drug[s]" upset that balance and are thus preempted. *Id.*; *Southeastern Pa. Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 702–03 (E.D. Pa. 2015) (state consumer protection law cannot be used to challenge a patent owner's "exercise of its exclusive patent rights to make pricing decisions"). Finding otherwise would mean that a State could sue whenever it does not like the price a manufacturer chooses to charge for an innovative product. That would not only violate the Constitution's Supremacy Clause, but also severely curtail the ability of manufacturers to develop new life-saving medicines for patients.

* * *

Because the State's claims as to GLP-1s are both inadequately pled and preempted, the Court should grant leave for Manufacturer Defendants to file a motion for partial judgment on the pleadings. Resolving this motion as to Mississippi's case will more broadly aid in determining the parameters of this MDL and will meaningfully facilitate the parties' discussions about the scope of discovery.

Respectfully submitted,

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